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101

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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FILED
M. DAVIS, HOFF, HENDON, ...
DUBOIS, DONNE, DUBOIS & MATHEU, ...
P.O. Box 101
ALEXANDRIA, VA 22304-0101

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

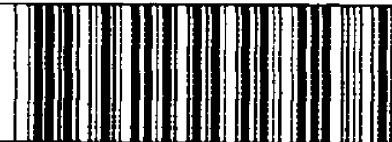
Office Action Summary

Application No.
09/132,231

Applicant(s)
Horwitz et al.

Examiner
John S. Brusca

Group Art Unit
1636



☒ Responsive to communication(s) filed on 9/24/99

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 3, 4, 6-8, and 11-25 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☒ Claim(s) 8 and 11 is/are allowed.

☒ Claim(s) 3, 4, 6, 7, and 12-25 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All ☐ Some* ☐ None ☐ of the CERTIFIED copies of the priority documents have been received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Information Disclosure Statement

1. The citation of Maniatis et al. in the information disclosure statement received 7/2/99 fails to comply with 37 CFR 1.98(a)(1), which requires a notation of relevant pages of the publication and a date and place of publication. The publication Maniatis et al. has been considered and placed in the application, but will not be made of record until a corrected Form PTO 1449 is furnished by the Applicant.
2. The citation of foreign patent numbers 3546806C2, 3546807C2, 3590766C2, and 2579618A1 in the information disclosure statement filed 7/2/99 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. The above foreign patents have been placed in the application file, but the information referred to therein has not been considered.

Specification

3. The Computer Readable Form of the Sequence Listing received 3/3/99 has not been entered for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules or CRF Diskette Problem Report.

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4. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR §§ 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR §§ 1.821-1.825 for the following reasons:

Several nucleotide sequences appear in the specification on pages 30, lines 14-15 and line 22 that are not properly identified. Nucleotide sequences must be identified by sequence identification number. Furthermore, if said sequences do not appear in the sequence listing, a new listing including said sequences must be supplied. It is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP 2422.02). If said sequences consist of a portion of sequences already of record in the sequence listing, they may be identified in the specification using the existing Seq ID No. accompanied by the position of the sequence on the already listed sequence.

Applicants are required to comply with all the requirements of 37 CFR §§ 1.821-1.825. Any response to this Office Action which fails to meet all of these requirements will be considered non-responsive. The nature of the sequences disclosed in the instant application has allowed an examination on the merits, the results of which are communicated below.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 3, 4, 6, 7, and 12-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3, 4, 6, and 13-25 are indefinite for recitation of the phrase "without regard to a wild type sequence" because it is not clear how the phrase limits the claimed nucleotide sequences. It is not clear whether the claimed sequences include wild type sequences as one of the possible members of the group of sequences, or whether the wild type sequences are excluded from the claimed group of sequences. The rejection would be overcome by deletion of the phrase from claims 3, 4, 6, and 13-25.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: identification of sequences which provide a desired biological activity. The rejection would be overcome by amending claim 7 to conclude with steps of screening vectors to identify isolates that provide a desired biological activity.

Claims 7 and 12 are indefinite for recitation of the phrase "the frequency of stop codons in said mixed population is reduced" because it is not clear what the reduction is relative to. The rejection would be overcome by amending claims 7 and 12 to recite "the

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frequency of stop codons in said mixed population is reduced as compared to codons encoding other amino acids."

Claim 14 is indefinite for recitation of the phrase "capable of." It is not clear if the claims are drawn to a latent property or a property that requires an additional agent for expression. The claim should be amended to distinctly recite the claimed properties using positive language.

Claim 24 is indefinite for recitation of the phrase "greater about a billion" because the meaning of the phrase is not clear. The rejection would be overcome by amending claim 24 to recite "about a billion."

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

8. Claims 3, 4, 6, 13-18, and 21-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Pieczenik.

The claims are drawn to methods of making, screening, and isolating populations of vectors that express a polypeptide with a biological activity, wherein the molecule is expressed

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from sequences isolated from a population of random sequences synthesized by enzymatic or chemical methods. In some embodiments the method isolates host cells comprising the selected vector, the polypeptide reacts with a substrate, the polypeptide is isolated, and the population of random sequences comprises about a billion members.

Pieczenik claims in claims 1-92 methods of making, screening, and isolating populations of vectors that express a polypeptide epitope, and the isolated polypeptides, wherein the epitope is expressed from sequences isolated from a population of random sequences. Claim 13 specifically teaches synthesis of the random sequence nucleic acid by chemical methods. Host cells comprising the random sequences are taught in claims 1, 23, 24, 34, and 90. In claims 47, 77, and 90 Pieczenik shows epitopes encoded by random sequences of nucleic acid that bind to an antibody, which is equivalent to the claimed polypeptides that react with a substrate. Pieczenik shows populations of vectors comprising random nucleic acid sequences or polypeptides with at least 10% of all possible random sequences in claims 10, 24, 34, 36, and 47, which is equivalent to up to 4×10^{15} peptides and up to 4×10^{21} nucleic acids.

9. The Declaration filed on 9/24/99 under 37 CFR 1.131 has been considered but is ineffective to overcome the Pieczenik reference.

The Pieczenik reference is a U.S. patent that claims the rejected invention. An affidavit or declaration is inappropriate under 37 CFR 1.131(a) when the patent is claiming the same patentable invention, see MPEP § 2306. The patent can only be overcome by

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establishing priority of invention through interference proceedings. See MPEP Chapter 2300 for information on initiating interference proceedings.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 3, 4, 6, 13, and 15-25 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 3 of U.S. Patent No. 5,824,469. Although the conflicting claims are not identical, they are not patentably distinct from each other because U.S. Patent 5,824,469 claims a species of the instant generic claims in which the biological property is a selectable property and the size of the random nucleic acids is limited to 54 or fewer nucleotides. The instant claimed methods of selecting host cells comprising random oligonucleotides are obvious variants of the method of selecting random oligonucleotides that are expressed in host cells of claims 2 and 3 of U. S. Patent No.

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5,824,469. The instant claimed methods of making and selecting an expressed product of a random oligonucleotide are inherent in the claimed methods of claims 2 and 3 of U.S. Patent No. 5,824,469. The claimed methods of selecting from a population of about a billion different random oligonucleotides are obvious over claims 2 and 3 of U.S. Patent No. 5,824,469 which teaches random oligonucleotide pools of 3×10^{32} members.

Conclusion

12. Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. For routine submissions the FAX number is (703) 308-4242. For FAX transmissions in cases in which the Examiner has been notified by phone to expect the transmission, the FAX number is (703) 305-7939. In such cases please call the Examiner at (703) 308-4231 at the time of transmission to expedite delivery of the fax. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6 (d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca, Ph.D. whose telephone number is (703) 308-4231. The examiner can normally be reached on Monday through Friday from 9 AM to 5 PM.

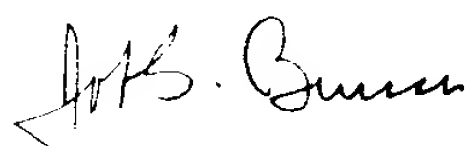
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, Ph.D., can be reached at (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



John S. Brusca, Ph.D.

Primary Examiner